K070430

APR - 4 2007

8.0 510(K) SUMMARY
Date Prepared: January 25 2007

8.1 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By: John M. Lindskog
General Manager
Unomedical A/S
Infusion Devices
Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark

8.2	Trade/Proprietary Name:	Paradigm Quick-Set® II and Quick-Set® II Subcutaneous Infusion Sets
8.3	Common/Usual Name	Subcutaneous Infusion Set
8.4	Classification Name	Intravascular Administration Set

8.5 Substantial Equivalence
The Paradigm Quick-Set® II sets are substantially equivalent to the current Paradigm Quick-Set® (K011071) sets. The Quick-Set® II sets are substantially equivalent to the current Quick-Set® (K991759) sets.

8.6	Classification	Class: II Panel: 80 Product Code: 80FPA Cite: 21 CFR 880.5440

8.7 Technological Characteristics
The Quick-Set® II Infusion Sets have the same technological characteristics as the current marketed products.

8.8 Performance Data
Verification testing confirmed the product meets their specifications.

8.9 Conclusion
Unomedical A/S concludes based on the information presented that the new products lines are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John M. Lindskog
General Manager
Unomedical A/S
Infusion Devices
Aaholmvej 1-3, Osted,
DK-4000 Roskilde,
DENMARK

APR - 4 2007

Re: K070430
Trade/Device Name: Paradigm Quick-Set® II and Quick-Set II®
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 25, 2007
Received: February 14, 2007

Dear Mr. Lindskog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K070430

Device Name: Paradigm Quick-Set® II and Quick-Set® II

Indications For Use: These sets are indicated for the subcutaneous infusion of medication, including insulin from compatible infusion pumps.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible]ion of Anesthesiology, General Hospital,
[illegible]ection Control, Dental Devices

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